

REMARKS

Claims 1-36 have been cancelled and new claims 37-50 have been added. No new matter is presented by virtue of the within amendments; support therefore can be found throughout the specification and original claims of the application. For instance, support for the subject matters of the newly presented claims can be found in the specification at least at page 11, line 36 to page 12, line 2; page 33, lines 8-35; Working Example 36 on page 82; and in original claims 17, 21, 32, 33 and 34.

Referring now to the Office Action, claims 1-36 stand rejected on several grounds – a summary of which follows:

1. Claims 21-34 are rejected under 35 USC 112, first paragraph.
2. Claims 1-36 are rejected under 35 USC 112, second paragraph.
3. Claims 26-30 are rejected under 35 USC 101.
4. Claims 1, 5-8 and 21-35 are rejected under 35 USC 102(b) over Yukimasa et al., WO 95/21834.
5. Claims 1, 5-8 and 21-35 are rejected under 35 USC 102(e) over Yukimasa et al., USP 5,726,306.
6. Claims 1-8 and 20-36 are rejected under 35 USC 102(e) over Hamanaka et al., USP 6,537,987.
7. Claims 1-36 are rejected under 103(a) over Yukimasa et al., EP 0 567 026 (US Equivalent of USP 5,885,979 and USP 5,726,306).
8. Claims 1-8 and 20-36 are rejected under 35 USC 103(a) over Hamanaka et al., USP 6,537,987.
9. Claims 16-18 are rejected under 35 USC 101 as allegedly claiming the same invention as claims 16-18 of prior USP 6,613,761.

10. Claims 31-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-4, 6, 7, 9-15, 17-19, 22 and 25 of USP 5,885,979.
11. Claims 1-9, 11, 14, 15, 17, 18, 20-25, 31, 34 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-4 and 8-16 of USP 5,726,306.
12. Claims 1-18, 20-25, 31-34 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-7 of USP 6,110,909.
13. Claims 1-15 and 19-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-15 and 19-27 of USP 6,613,761.
14. Claims 1-34 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-33 of copending application no. USSN 10/480,707.
15. Claims 1-34 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-52 of copending application no. USSN 10/416,329.
16. Claim 35 is objected to for lacking proper dependent form.

These several rejections are believed to be overcome and/or rendered moot in view of the within amendments. For instance, original claims 1-36 have been cancelled and new claims 37-50 are presented. The newly presented claims are directed to the combination of a single preferred compound:

N-[(3R,5S)-1-(3-Acetoxy-2,2-dimethylpropyl)-7-chloro-5-(2,3-dimethoxyphenyl)-2-oxo-1,2,3,5-tetrahydro-4,1-benzoxazepine-3-acetyl]piperidine-4-acetic acid, or a salt thereof,

with one or more agents for controlling the biosynthesis of cholesterol [as recited in independent claim 37].

Additional preferred embodiments of the present invention also are claimed wherein the agents for controlling the biosynthesis of cholesterol are further defined as HMG-CoA reductase inhibiting agents and statins, including lovastatin, simvastatin and pravastatin. Related methods also are presented in new claims 43-50. As indicated above, ample support for the newly recited subject matters can be found in the specification and original claims of the application.

Reconsideration of the application is respectfully requested in view of the within amendments. Withdrawal of the afore-mentioned rejections is believed to be proper. Indeed, in view of the above arguments and amendments, Applicant believes the pending application is in condition for immediate allowance which action is earnestly solicited.

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Respectfully submitted,

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